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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,582	12/20/2001	Patrick Soon-Shiong	VIVOR1420-1 (073799-1107)	6249

30542 7590 04/21/2003

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EXAMINER

JONES, DAMERON

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/21/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,582

Applicant(s)

SOON-SHIONG ET AL.

Examiner

D. L. Jones

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-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/20/01; 6/14/02; and 1/21/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 39-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 39-52 and 54-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 1 ½, filed 12/20/02, wherein claims 7-38 were canceled.

Note: Claims 1-6 and 39-64 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group VII (claim 53) in Paper No. 4, filed 1/21/03, is acknowledged. The traversal is on the grounds that a search of the all the claims is not a burden on the Examiner. In addition, Applicant asserts that a search of art related to microcapsules would presumably result in information useful to consider all claims directed to microcapsules. This is found non-persuasive because all the microcapsule claims do not have the same limitations. For example, various methods of making microcapsules are disclosed wherein in a gellable material is present in some while not in others. Thus, art (as cited in the rejection below) may be used to reject claims wherein a gellable material is not a claim limitation. In regards to Applicant's assertion that it is not a burden to search all the claims, the Examiner is not persuaded for the reasons previously stated. Also, it is noted that limitations present in some claims for which art is cited neither anticipate or render obvious other limitations. Thus, since the claims do not contain the same general limitations, additional searching and consideration is necessary. Furthermore in some claims, at least one cell aggregate is required in the core while others are directed to a biologically active agent which

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encompasses a multitude of possible agents. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

WITHDRAWN CLAIMS

3. Claims 1-6, 39-52, and 54-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

103 REJECTIONS

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dionne et al (US Patent No. 5,874,099).

Dionne et al disclose a product comprising a biocompatible jacket and matrix core (see entire document, especially, abstract). In particular, their invention is directed to an implantable vehicle that comprises a core which contains isolated cells, either suspended in a liquid medium or immobilized within a hydrogel matrix and a surround region which does not contain isolated cells, but is sufficient to protect the isolated cells in the core (column 3, lines 19-46). In addition, Dionne et al disclose that the core may be composed of a matrix formed by a hydrogels which stabilized the position of the cells

in cell clumps. The hydrogel is composed of crosslinked hydrophobic polymers (the network is in the form of a gel substantially composed of water) [column 6, lines 39-57]. The surrounding region may be formed freely around the core without chemical bonding or the jacket may be directly crosslinked to the core matrix. In addition, the region may be of a hydrogel matrix or of a different material. Likewise, the surrounding region may be used in the microcapsule field and crosslinked with a multivalent ion such as calcium. The core and surrounding region form an interface free of ionic bonding between oppositely charged polymers and free of an intermediate layer of the type used in prior art microcapsules (column 15, lines 16-44).

It would have been obvious to one of ordinary skill in the art to modify the invention of Dionne et al and generate a microcapsule containing at least one cell aggregate where the core of the microcapsule is not ionically crosslinked and the outer layer is covalently crosslinked or polyionically crosslinked or both covalently crosslinked and polyionically crosslinked, but not ionically crosslinked for the reason below. (1) The invention of Dionne et al is directed to a product (e.g., microcapsule) wherein the core contains isolated cells and the surrounding layer is a matrix or membrane that is permselective. (2) The core may be a gel matrix formed by a hydrogen composed of crosslinked polymers wherein the gel is substantially formed of water. (3) The outer layer of the product may be formed freely around the core without chemical bonding or may be directly crosslinked to the core. (4) The outer layer may be crosslinked with a multivalent ion such as calcium. Hence, a skilled practitioner in the art would recognize that since Applicant has set forth definitions that (a) not ionically crosslinked is

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interpreted as an insufficient amount of multivalent cation(s) are present to substantially crosslink the material, then Dionne et al cell containing core fulfills the core requirements of the instant invention. (b) Likewise, since Dionne et al disclose that the surrounding (outer) layer may be crosslinked with a multivalent ion, then the outer layer requirements of the instant invention are fulfilled.

SPECIFICATION

6. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This application is a divisional of Application No. 09/264,187, now US Patent No. 6,495,161, filed 3/9/99." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

COMMENTS/NOTES

7. It should be noted that if Applicant's product (claim 53) should be found allowable, then at that time, the Examiner will allow Applicant additional claims (e.g., method claims) directed to that product. However, Applicant is reminded that the methods MUST contain ALL the limitations of the product claim.

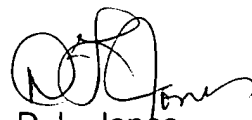
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640.

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The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones
Primary Examiner
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April 21, 2003